Participant Information Sheet

Study title

CONNECT: using electronic devices (e.g. smartphones, smartwatches) to predict relapse of psychosis.

Invitation to take part in research

You are being invited to take part in a research study using a smartphone and wrist-worn activity tracker to look at things like your sleep patterns, activity levels, phone usage and social behaviour, and to see how changes in these might relate to your mental health. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

Why have I been invited to take part?

You are being invited to take part in this study as you are 16 or over, use NHS mental health services and receive or have received treatment for psychosis. You may have taken part in another psychosis research study and agreed to be contacted by researchers about other projects.

What is the purpose of the research?

People who have experienced psychosis can experience changes in their activity levels, mental health, sleep pattern and social behaviour when they feel they are becoming unwell. For example, someone who is feeling very anxious or low might not feel like socialising much. They might stay at home more than usual, phone their friends less, sleep less, and experience other changes they do not wish for.

We would like to see how easy or difficult it is for people who have experienced psychosis recently (in the past two years) to use a smartphone and wrist-worn activity tracker to look at things like their sleep patterns, social behaviour, phone usage and mental health, and to see how changes in these might relate to whether their mental health gets better or worse.

In the future, it might be possible to tell in advance when someone's mental health might be getting worse by looking at this type of information and offering extra support.

What would I be asked to do if I took part?

1. **Give consent /agree to take part in the study**
2. **Provide some information about your mental and physical health, your background, your living environment**
3. **Wear either a fitness tracker or a smartwatch on your wrist (we will provide it)**
4. **Download and use the CONNECT smartphone app (we can provide a smartphone for this), and answer a short set of questions throughout the week**
5. **Stay in contact with the study team via phone and online, mainly once a month**
6. **You will get paid £20 for attending a 90 minute meeting every 4 months, we will pay network costs of £10 per month for the time you are taking part in the study (up to 12 months).**

Further information

If you decide to take part in this research study, first we will check with you that you have read this information sheet and the consent form and whether you have any questions. Once you have had all your questions answered satisfactorily, we will then ask you to formally agree or consent to take part in the study. You can choose how you would like to give your consent:

- via a web link or email
- a paper consent form that you can return via pre-paid post or hand to a researcher if meeting in person
- audio recorded consent where a researcher will read out each statement from the consent form and ask you to verbally agree 'yes' or disagree 'no' with each statement.

After you have given consent, we will ask for some information about your mental and physical health, your background, your living environment, and we will ask you to complete some questionnaires.

We will inform your GP and care coordinator that you are taking part in the study. Individuals from the research team will access your medical records to collect the information for the study.

At most study sites, a clinician directly involved in your care will give you initial information about the study. At Greater Manchester Mental Health, the first approach may come from a member of staff called a Research Practitioner, who might check your medical record before speaking to you to see if you are eligible to take part in the study. If you would like more information about this, please contact the CONNECT project manager, whose details are on p.12 of this information sheet.

Wear either a fitness tracker or a smartwatch on your wrist (we will provide it)

Depending on the type of phone you have, you will be given either a fitness tracker or a smartwatch to wear on your wrist (called a 'wearable device'). You will be asked to wear the device on your wrist whenever possible, ideally taking it off only for charging and when taking a shower, bath or swimming. It will need to be charged regularly and you will be asked to wear it for up to a year. If you already own a wearable device, you can continue to wear it if it works with the CONNECT app (described below). If the wearable device you already own doesn't work (is not compatible) with the CONNECT app, we will offer you a wearable device to use. We do understand that there will be times when you want or need to take the wearable device off – and that's fine. At the end of taking part in the 12-month study, you can keep these devices.

Download and use the CONNECT smartphone app

We will also help you download and install the CONNECT app onto your own smartphone. The CONNECT app will prompt you throughout the week and ask you to rate questions about things like your symptoms and mood. You can pause these prompts if you wish to take a break at any time. If you do not own a smartphone, we will give you one with the CONNECT app pre-loaded. We will spend some time with you explaining how the smartphone and wearable device works, how to look after and charge the devices, and how to use the CONNECT app. This will take approximately 1.5 hours.

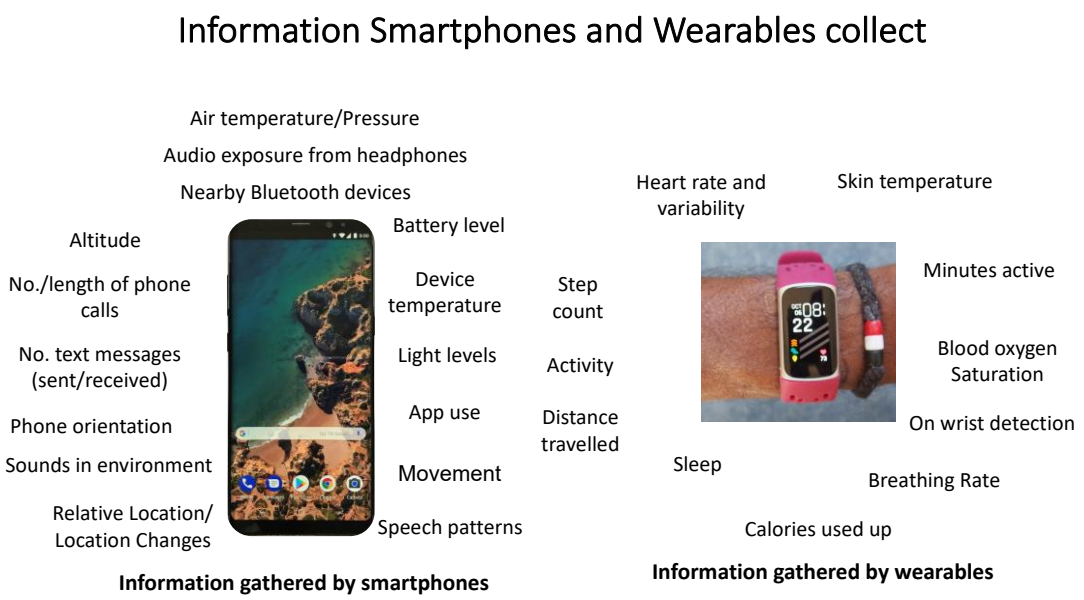
You will be asked to carry your smartphone with you at all times for the duration of the study, but we understand that this may not always be possible. We will ask you to keep your normal daily routine. We will pay £10 per month for your data network cost for the time you are using the CONNECT app (up to 12 months). You will need to charge the phone as normal. You will also be asked to give your permission for the app to access sensors and data on phone usage, but this is optional – you can say no to this. The app will send the information the smartphone, app and wearable device collects to us using a WI-FI connection and will only use cellular data services if you enable it.

What information will be collected (and not collected)

Almost all smartphone apps and wearable devices collect information about you. This can include things like your location, age and your gender. We **will not** collect information that can directly identify you. For example, we will be able to see how active you have been or how far you have travelled in a day but not your precise location or home address, and we **will not** be able to see where you have travelled in real time. While we collect information about the number of text messages or emails you send, or the length of your phone-calls, we **will not** be able to see the content of the messages, the content of your calls or the name or number of the person you have contacted. We **will not** access any other information, such as the content of in-person conversations, what websites you are visiting, or your photos. If you use an iPhone, we will collect information about the speed and pattern of your speech, such as words per minute and how long between words. We **will not** be able to know what you are saying. A full list of the data collected from the phone and wearable device is available on request.

If you find any aspect of taking part in the study stressful, upsetting or uncomfortable, you are free to stop without having to give a reason and without this effecting your care. If you would prefer to only have data collected via either a smartphone or a wearable, you can still participate in the study.

Here is a diagram of the information that can be collected from the smartphone and wearable device.



The wearable device will automatically (i.e. without you needing to do anything) collect information about things like your movements and heart rate. From this information, we will be able to work out, for example, your level of physical activity and sleep patterns. We will collect information automatically using sensors which are built into all modern smartphones. Some information about your environment, location and phone usage will be collected.

The CONNECT app will also ask you to complete a short series of questions throughout the week about your symptoms, mood, environment, and activities. This will take only a few minutes to complete. If you happen to be busy you do not have to respond to the questions straight away – there is a snooze function. You can choose how often we send an alert notification to you; this can range from 3 to 7 days per week. You can pause the notifications for a period if you like.

The smartphone and wearable are not emergency devices, and your clinical team will not have access to any data entered into them.

How will the study team keep in contact with me

You will be given the contact information for the research team in case you have any problems. There are contact details of people that you can talk to if you have any questions about taking part in the study at the end of this sheet.

Contact with the research team

You would take part in the study for one year. We will call you weekly for the first month, then every month after that, to make sure that everything is OK and that the devices are working correctly. We will provide you with an App and Wearable Guide which includes commonly asked questions and guidance on using the CONNECT app, wearable, and CONNECT phone. If you have any problems with the devices, you can contact a member of the research team and they will work through the problem with you. If they cannot solve the problem immediately, they might arrange a meeting for both of you with a member of the software team to try to solve the problem. If we stop receiving information

from any of the devices, we may get in touch to check that they are still working and to find out if you're having any problems. You will not be able to see your data during the study period but we will give you the opportunity to see your data at the end of the study period.

4-Monthly check-ins

Every four months, we will ask you to complete some questionnaires about, for example, your symptoms, mood, technology use and quality of life. This is so we can see how things might have changed for you since you started taking part in the study. This should take around 1.5 hours to complete. You can complete these questionnaires either over the phone with the support of a research worker, via online conferencing (e.g. Zoom / Microsoft Teams / NearMe), in person (at your home, at a nearby NHS service or University building), or via a secure website. This depends on your preference and taking into account any COVID-19 restrictions at the time.

The researcher will check that you fully understand what is involved in the study and remain willing to take part before each session. We would also like to access your medical records over the course of the study to note down information such as whether you have been in contact with mental health services, whether there have been any changes in your mental health or your treatment since taking part in the study, and whether information in your medical record helps us better understand if we can predict relapse. To do this, we need to access information held by NHS England/NHS Scotland/NHS Wales and/or your local Integrated Care Board/Health Board and link this to the information we have already collected from you. Access to this information is optional, will only be carried out for the study, and there will be no further access once the study ends.

Additional support and your care

After each meeting, the researcher will give you an information sheet with details of organisations and helpful numbers you can contact if you need support (e.g. Mind, The Samaritans). The researcher will also offer to phone you a day or two later to check if you have any concerns or further questions about the study.

The information you share during the study will be kept confidential and stored securely. However, we may need to pass on some information to another person (e.g. your GP or care co-ordinator) if we have serious concerns about your safety or the safety of others. We will tell your care team you are taking part in the study and add a note to your medical record reflecting this. Taking part in the study will not affect your usual care.

What will happen at the end of the year?

At the end of the study period, you will be given the opportunity to see and discuss the information collected about you with the research team and debrief about the study. This will take up to 1 hour and will take place either remotely (e.g. Zoom / Microsoft Teams / NearMe / Over the phone) or in person (at your home, at a nearby NHS service or University building), whichever you prefer.

We may also ask you to participate in an additional interview to find out more about your experiences of participating in the study. With your permission, we will audio record the interview. If you feel uncomfortable about being recorded at any time during the interview, please tell the researcher so they can stop the recording. The interview will be done either over the phone with a research worker, via online conferencing (e.g. Zoom / Microsoft Teams / NearMe), or in person (at your home, at a

nearby NHS service or University building), whichever you prefer, and will last up to 1 hour. We will ask what it was like for you to take part in the study and about any improvements that can be made.

If you decide to stop using the app before the end of 12 months, we might still ask you to fill out some questionnaires and tell us how you found the study, as your feedback is important to us. You will be able to refuse to be interviewed without this impacting on your participation in the rest of the study or on your clinical care.

Who will conduct the research?

Professor Sandra Bucci is leading this research. Prof Bucci is based at the University of Manchester, in the Division of Psychology and Mental Health, School of Health Sciences. This research is sponsored by The University of Manchester.

The study will run at six sites. The study sites, and people leading at each site, are:

- University of Manchester — Professor Sandra Bucci
- University of Glasgow — Professor Andrew Gumley
- University of Edinburgh — Professor Matthias Schwannauer
- Cardiff University — Professor James Walters
- King's College London — Professor Dame Til Wykes / Dr Matteo Cella
- University of Sussex — Professor Kathryn Greenwood

A charity called the McPin Foundation (www.mcpin.org) is providing the service user involvement for the study.

Am I suitable to take part?

We are aiming to recruit approximately 1100 people who have recently experienced psychosis (in the past 2 years), are currently in contact with mental health services, are aged over 16 years, and who feel able and willing to participate.

Will the research findings be published?

We will send a leaflet summarising the results in a clear and accessible way to study participants who would like to receive it. We will present the results at research meetings, conferences and other events for stakeholders, policy makers and the wider public. We will publish the study findings in scientific journals, on our website and data may be used for student projects. You will *not* be identified personally in any report or publication.

Disclosure and Barring Service (DBS) Check

All researchers have undergone satisfactory DBS and/or Disclosure Scotland checks.

Who has reviewed the research project?

This study has been reviewed by the West Midlands – Black Country Research Ethics Committee (REC reference number: 23/WM/0044) and the Health Research Authority (HRA).

Who is funding the research project?

This research is funded by The Wellcome Trust.

Are there any benefits in taking part?

Participating in this study will not cure or treat psychosis. We hope our meetings and interviews will provide an open and comfortable space in which you can feel free to share your thoughts, feelings, and opinions. Participating in research can be rewarding, and you will be contributing to the development of **new knowledge** which could benefit other people in the future. The information you give us might mean that in the future we will be able to tell in advance when someone's mental health might be getting worse and offering extra support to keep people safe and well, at the time it's needed.

At the end of the study, we will give a summary of your information and an opportunity to talk about it with the research team. Learning more about how your sleep, thoughts and feelings, behaviours and phone usage relates to your mood and symptoms could give you important insights into staying well in the future.

Reimbursement and travel expenses

You will be reimbursed for any reasonable travel undertaken in this research study (e.g. travel to and from meetings). You will receive £20 for attending the initial meeting and meetings every 4 months after that (up to £80, using vouchers, in cash or via a bank payment). If you are invited to participate in an interview, you will be paid an additional £20. If you don't have a smartphone or the type of wearable device we are using in this study, we will give them to you to use. At the end of taking part in the 12-month study, you can keep these devices. We will pay £10 per month for your network costs for the time you are using the CONNECT app (up to 12 months). We will also teach you how to use a smartphone and wearable device.

Are there any risks and disadvantages in taking part?

- You may find using the wearable device, or answering questions on the CONNECT app, difficult or unsettling. If you do, you will be able to discuss this with a member of our team or with an NHS professional you already know. We will try to help you feel at ease and remind you that you do not have to answer any questions you do not want to. You can ask the researcher to move on or stop the assessment altogether if you find any of the questions upsetting. We hope this study will help us learn how to make the app and wearable easier to use, and will ask you about any difficulties at the end of the study.
- Some people may feel uncomfortable having some information about their sleep or location collected. We will make sure to explain exactly what data is being collected, and how we will protect your confidentiality. A full list of the data being collected is available on request. You can also contact us at any time if you feel unhappy about any part of the study.
- The wearables used in this research are very safe; they are commercially available devices and have undergone extensive safety testing. There is a very small chance you may develop a skin rash on the part of the wrist where the wearable device is worn, in which case you can remove it. We also ask that you do not complete the questions on the smartphone apps when in a situation where you need to pay attention, such as driving or crossing the road.

- There is a small risk that the technologies used in this study could be hacked. If this occurred, we will immediately follow relevant procedures to fix this. However, this risk is the same as with any smartphone or commercial fitness tracker use. The encryption and data de-identification processes have been put in place to minimise any risk to you in the unlikely event of hacking.

What happens if I do not want to take part?

It is up to you to decide whether or not to take part. Whether or not you decide to take part will not affect the healthcare you receive in any way. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form / provide audio consent. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised at the end of the study as we will not be able to identify your specific data. This does not affect your data protection rights. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team but you still have rights to complain to our Data Protection Officer and if you are still not satisfied you also have the right to complain about this to the Information Commissioner.

If you decide not to take part in the study, you do not need to do anything further. This will not impact on any services you are currently receiving or may receive in the future.

If you take part then decide you don't want to anymore, we would like to ask you about why you decided to stop taking part. This is mainly for our own learning, but we will only ask you about this if you consent to the interview. It is completely your choice.

You will not be withdrawn from the study if you experience a relapse of psychosis. However, in the unlikely event that you lose capacity to consent during the study, you will be withdrawn from the study, but any data collected up until this point may still be used - but we will not collect any further information.

What information will you collect about me?

In order to participate in this research project, we will need to collect information that could identify you, called 'personal identifiable information'. Specifically, we will need to collect:

- Name and preferred contact details (e.g., postal address, email address, phone number).
- Demographic information: e.g. age, gender, ethnicity, marital status, employment status, education level, and whether you live alone or with other people, whether you have caring responsibilities), medical history.
- NHS number.
- GP and care co-ordinator contact details.
- An audio recording of your voice if you are invited to take part in an interview.
- Record of consent (e.g. online, paper, electronic via email, audio).

If you choose to take part in an interview, or provide audio consent, we will record voice only unless you choose to use MS Teams. In this situation, we will ask you to switch off your camera so that we do not record your face. A video will be recorded, and the audio will then be separated from the recording, and the original recording destroyed.

All personal identifiable information will be held by your local research site. We will also collect data about you that is not personal identifiable information:

- Mental health diagnosis.
- Medical information*.
- Your response to the research interviews and questionnaires.
- Information from your smartphone: distance travelled, light levels, weather information (e.g. air temperature, humidity), magnetic field, steps, phone use (e.g. number/length of phone calls; number of text messages sent/received), Bluetooth connectivity, app use, battery level.
- A record of which parts of the app you use and when, collected using secure software. We also collect information that enables us to provide technical support for the app.
- Information from a wearable device: physical activity summary, heart rate, sleep, steps, skin temperature, distance travelled.

* If you decide to no longer take part in the study, we might still collect information from your medical records for the time you were in the study up to the date you withdrew unless you ask us not to or have asked us to delete your data.

This non-identifiable information will be held by the University of Manchester for all participants. This is the 'study data'.

Information from your wearable device will be processed differently depending on the manufacturer. With Apple watches and Android smart watches, you will be asked to give the CONNECT app permission to access the data they collect. If you choose a *Fitbit*, you will be required to register for a *Google Health* account, and will be asked to provide your name, email address and date of birth. Your data will be stored on the *Google Health* database as well as by us. You can ask for your data to be deleted from the *Google Health* database at the end of the study.

Under what legal basis are you collecting this information?
We are collecting and storing personal identifiable information in accordance with UK data protection law which protects your rights. This states that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is 'a public interest task' and 'a process necessary for research purposes'.

What are my rights in relation to the information you will collect about me?
You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings. This is known as a Subject Access Request. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research which can be accessed here: https://documents.manchester.ac.uk/display.aspx?DocID=37095. Sometimes your rights may be limited if it would prevent or delay the research. If this happens, you will be informed by the research team.

Will my participation in the study be confidential and my personal identifiable information be protected?
In accordance with data protection law, the recruiting site is the Data Controller for your personal identifiable information. This means that they are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the ways described below. If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/

The University of Manchester is the data controller for the study data.

De-identification of study data
The researchers will allocate each participant a unique participant ID number. The study data will then be referred to by the participant ID number only. The information collected from the app, smartphone and wearable device will only be associated with this ID number. Only the research team will have access to the key that links this ID number to your personal information. The key will be stored electronically and separately from other research data and deleted at the end of the study. After this, we will not be able to identify your specific data (i.e. the data will be anonymous). Information from the wearable and CONNECT app will be sent to the research team in an **encrypted** form.

Data storage
We will store personal data (e.g. name, address, audio-recordings) separately from study data:

- We will store personal data (e.g. name, address, audio-recordings) on secure university/NHS electronic storage (e.g. secure server) according to local information governance procedures (e.g. password protected files). If you choose to complete a paper consent form, we will store it in a locked filing cabinet in a locked university/NHS office.
- We will store de-identified data (e.g. interview transcripts) on a password-protected university/NHS computer, secure university/NHS electronic storage (separate from personal data) or secure, password-protected laptop.
- Data from the app, smartphone and wearables will be **securely** stored on Amazon Web Services supported by a University of Manchester approved IT supplier. This data cannot be linked back to your personal identifying information. No personal identifying data is stored on these servers. AWS is a secure cloud hosting service; their servers are located in the London Region and are therefore subject to UK law.

- Data collected at assessment time-points will be **securely** stored in a research database on UoM servers. No personal identifying data is stored on these servers.

Only the research team will have direct access to personal information and study data*. However, study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities, from the relevant Higher Education Institution (HEI) or from the NHS Trust (or NHS Health Board) to make sure the project is being carried out as planned and meet high standards of safety and security; this may involve looking at identifiable data. They will need to apply to the research team to access the data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

*Note: If you choose to receive the £20 study payment using an electronic voucher, we will share your email address with our university / NHS Finance department who will send the voucher to you. Your email address will be kept securely by Finance for a period of up to 7 years for audit purposes only, and then destroyed. It will not be used by them for any other purpose.

At the end of the study, all de-identified study data will be archived by the study Sponsor (University of Manchester). It will be safely stored for up to 20 years and then destroyed. We will keep consent forms (and consent audio recordings) as essential documents for up to 2 years after the study has ended. We will delete other personally identifiable information (e.g. contact details and audio recordings) as soon as they are no longer needed as required by data protection law.

With your consent, we would like to keep your contact details for 5 years to provide you with a summary of the findings for this study and/or to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored, only accessible to the research team, and only used for the purposes described above.

Audio recordings

If you take part in the interview at the end of the study, we will audio record it (and informed consent, if you choose this) using either: an encrypted audio recording device (e.g. Dictaphone), or an online meeting platform (Zoom / Teams).* We will follow University of Manchester guidance for audio recordings for research purposes. Audio recordings are personal data and will be processed and stored accordingly. As soon as possible after the interview has finished, the researcher will transfer the audio recording of the interview (and audio-recorded informed consent, if applicable) to a secure server at the relevant site and then remove it from the recording device. Where applicable, audio-recorded informed consent will be stored on a secure server at the research site, separately from the main interview.

* Extra information about audio recording using an online meeting platform. If you give permission for us to record the interview in Zoom / Teams, your personal data will be processed by Microsoft / Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on a secure university/NHS server as soon as possible after the interview ends.

Transcription of audio recordings

If you participate in an optional interview to tell us about your experience of participating, the interview recording will be transcribed (i.e. speech will be typed out as text in a document). Any personally identifying details (e.g. names, specific places) will be removed from the final transcript. As with other de-identified study data, the transcript will then be referred to by the participant ID number only. Transcription may be carried out by the study team, by an approved individual based at the University of Manchester (outside the research team), or by anexternal transcription service. Anyone outside the research team will sign a confidentiality agreement before listening to the recording and will not have access to other personal data (e.g. name, address). Where an external transcription service is used, this must be on the list of services approved by the University of Manchester, and audio files will be transferred using a secure file transfer system (also approved by the University of Manchester). We will then use the secure file transfer system to transfer these transcripts to The University of Manchester for storage.

Data sharing

At the end of the study, completely anonymised study data will be made available to other researchers (including research students) - you will not be identified in this. They will need to apply to access the data. This will support additional research in accordance with the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)**.** Your information could be used for research in any aspect of health or care.

We will ask for your additional consent to link your study data with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you. Where there is a risk that you can be identified, your data will only be used in research that has been independently reviewed by an ethics committee.

Potential disclosures

In certain circumstances, the researchers may need to disclose information to another person or a relevant authority. We will speak to your care team or GP if there are significant concerns about you (including if you experience any significant distress while taking part) or someone else's safety. We will take all possible steps to discuss this with you first.

If, during the study, you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities.

Individuals from the University, the site where the research is taking place, and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident.

What if I have a complaint?

If you want to make a complaint that you wish to direct to members of the research team, please contact:

CONNECT Project Manager	CONNECT Chief Investigator
Dr Jane Lees	Professor Sandra Bucci
Jane.lees@manchester.ac.uk	Sandra.bucci@manchester.ac.uk
0161 529 3834	0161 306 0422

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you gained from the researchers in the first instance then please contact:
The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information: https://ico.org.uk/make-a-complaint/ Tel 0303 123 1113

Harm

In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or Greater Manchester NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Contact Details for queries

If you have any queries about the study and/or if you are interested in taking part, then please contact the researcher(s)

Research Assistants Natalia Cross – 07393 466 702 Josh Barber - 07385 227 425 connect@gmmh.nhs.uk	Research Coordinator Clare Murray connect@gmmh.nhs.uk 07385 407 483